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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Volker Buhren

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05/30/2006

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EXAMINER

KIM, JOHN

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/803,638	Applicant(s) BUHREN ET AL.	
	Examiner John Kim	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Examiner's note

It is noted in the office action dated 12/15/05, examiner objected to the drawing, but did not state the reason for the objection. Applicant's representative telephoned in regards to the drawing objection and it was discussed that figure 12 failed to show clearly the distinctive features of reference 62 and 61, in comparison to figure 5.

Applicant has submitted new drawing to overcome that objection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bono (US Pat 5954722).

Claim 1: Bono teaches of having an elongated load-bearing element (10) with openings (14) for a fixation element (18) and an insert (16) complimentary of the receptacle of the opening, and where the insert has a means for being locked to the load-bearing element. Furthermore, Bono shows in figure 5 that the openings are not truly flat, but instead there is a hollow or alcove to allow the insert to rotate in entry angle (compare 26 to 28, one notices the recess at 28). This is complementary to Bono's insert. Claim 5: Bono teaches that the insert (16) possess "the mechanical properties suitable for frictionally engaging locking plate (12)." (col 4:30-34) Claim 10,

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Bono teaches: "while bushing 16 is illustrated with a spherically-shaped and smooth exterior surface 28, it is understood that exterior surface 28 may be formed in a variety of rounded shapes and sizes to cooperate with internal wall 26 of locking plate 12." (col 4:, 6-8, 41-45) Thus Bono teaches the insert and opening can be elongated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 4, 6, 7, 9, 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Bono (US Pat 5954722) in view of Haag et al. (US Pat 5976141).

Bono discloses an elongated load-bearing element with a lockable insert. He further discloses the element with apertures sharing a central axis with the insert (claim 12, see Bono figure 5) and the aperture in the form of an elongated slot (claim 13, discussed above for claim 10). However, Bono fails to disclose his insert having the limitations as stated in the application: an insert with an extension (or a resilient extension) (claim 2 and 11), a projection in the locking mechanism (claim 4), a locking mechanism that interacts in the area of the underside of the load-bearing element (claim 6), a recess on the underside, an insert that deviates from the normal axis (claim 7), and having an insert with an inclined axis (claim 9) and a locking surface with a ledge (claim

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15). These limitations, as listed above, are disclosed by Haag and will be discussed individually below.

Haag discloses a threaded insert for a bone plate as opposed to the whole device of a plate and insert. Claim 2, 3, 4: Haag teaches his insert of having a locking mechanism, extension, projection (22, see figure 2) and since the insert is slotted (21), is is flexible. Haag also teaches the insert having a groove (23). The extension, projection, and groove of the insert interact with the complimentary area of the opening on the plate. This interaction allows the insert to be locked in place on the plate. Claim 5: Haag teaches of having a locking mechanism fixed against the load-bearing element used with a fixation element (200). (col 6: 11-13, 21-37) This allows the surgeon to lock the bone anchor with the insert. Claim 6, 7: Haag teaches the locking mechanism being able to interact with the complementary area (104, 106 figure 3) in the area of the underside of the load-bearing element. The recess (106) engages the locking mechanism, and thus the insert does not extend beyond the underside as seen in figure 4. This would allow a minimum distance between the bone and bone plate, thus minimizing the amount of damage to the body after the surgery. Claim 9: Haag teaches of having the insert at an inclined axis as seen in figure 8 (col 6:52-63). This would allow the surgeon to enter the bone anchor at a preferred angle.

Claim 11: Bono teaches of having a plate (10), with apertures (14) (a recessed outwardly facing surface and sidewalls), where the sidewalls extend from a bone contacting surface (bottom of the plate) to the outwardly facing surface, and insert (16) with a threaded body (38). However, Bono fails to teach of having an insert with a

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resilient extension. Haag teaches his insert having an outer surface that will engage the aperture's inner surface, which has a locking surface, and the insert having a resilient extension. The extension allows the insert to be locked to the plate. Claim 12: Bono teaches his insert and aperture having the same central axis. Claim 13: Bono, as stated above for claim 10, teaches that an elongated slot can be used as an aperture. Claim 14: Bono also teaches the insert being complementary to the aperture, thus would be elongated. However, Bono fails to teach about the resilient extension, as stated above. Haag teaches his resilient extension (20, figure 2 Haag) of the insert would extend between the two surfaces. As stated above, the extension is part of the locking mechanism to lock the insert to the plate. Claim 15: Bono fails to teach his aperture to have a ledge. Haag teaches of the aperture having a ledge (106) and the insert's extension has an outwardly extending lip (22). These structures would allow better interaction of fixating the insert with the plate.

It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Bono in view of Haag et al., in order to lock the insert with the bone plate. The purpose of these limitations, as stated above, is to allow the surgeon to lock the insert so that the bone screw is locked in relation to the bone plate with any preferred angle.

Response to Arguments

Applicant's arguments filed 3/13/06 have been fully considered but they are not persuasive.

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Applicant argues the prior art fails to have an opening with a recessed area in the opening that is complementary to the insert's surface (applicant's argument was a bit confusing as to what "they" and "its" was being referred to: inserts, side walls, bearing element, or plate). A recess is defined as an indentation, hollow or alcove. Bono shows in figure 5 that the openings are not truly flat, but instead there is a hollow or alcove to allow the insert to rotate in entry angle (compare 26 to 28, one notices the recess at 28). This is complementary to Bono's insert. Since the amendment overcomes Lin, that argument is moot.

In response to Applicant's argument that "the insert to be placed into the plate at any desired point during its use" are features/limitations not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. Furthermore, the language above (any point during its use) seems to be functional. It is noted that the invention is in regards to an apparatus or device. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. (See MPEP 2114)

In response to Applicant's argument that "the complimentary engaging surface allow load to be transferred to the outwardly facing surface of the plate..." are features/limitations not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. Again, the language of this argument seems to be functional; please read the paragraph above in regards to functional language.

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Though applicant is arguable correct that Haag et al. shows the insert has only a point contact to the sidewalls and thus may not be complementary, it is only the "snap" locking feature that is being combined with the complimentary surfaces of the insert and opening found in Bono. Thus applicant's argument is not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER